UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,539	05/30/2007	Peter David East	76786/JPW/CH	9795

23432 7590 07/06/2009

COOPER & DUNHAM, LLP
30 Rockefeller Plaza
20th Floor
NEW YORK, NY 10112

EXAMINER	
GANGLE, BRIAN J	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
07/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,539	EAST ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,6,8-18,20,21,23,25 and 27* is/are pending in the application.

4a) Of the above claim(s) *1,5,11,12,14,16-18,20,21,23,25,27 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,8-10,13 and 15* is/are rejected.

7)☒ Claim(s) *29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/13/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and remarks filed on 4/22/2009 and 4/28/2009 are acknowledged. Claims 1, 6, 11, 15, and 17 are amended. New claims 28-29 are added. Claims 1, 5-6, 8-18, 20-21, 23, 25, and 27 are pending.

Election/Restrictions

Applicant argues:

1. That the PCT rules for unity of invention (specifically section 10.59) state that where there is no prior art disclosing the claimed polynucleotide or peptide, the claimed polynucleotide or peptide share a corresponding technical feature, and consequently, the claims have unity of invention (*a priori*).

2. That the prior art relied upon by the examiner discloses a peptide having 33.3% identity to SEQ ID NO:4 over a very small 12 amino acid stretch, whereas the claims require at least 80% identity. Applicant asserts that this shows that there is no prior art disclosing the sequences in the claims.

3. That each of the claimed peptides is an alternative in a class of peptides sharing a common property and a common structure. Applicant asserts that the peptides share a long linear alpha-helical tertiary structure and have a consensus sequence shown in SEQ ID NO:62. Applicant asserts that this structure is entirely different than that disclosed by the prior art cited by the examiner.

4. That the examiner's assertion that the technical feature linking the sequences is that they are antimicrobial peptides from *G. mellonella* overlooks the feature that these peptides are related peptides which belong to a separate class of peptides from the defensin disclosed in the prior art.

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, applicant correctly refers to Example 39 of the PCT rules. However, applicant has incorrectly applied the example. First, there is prior art, as will be discussed below with regard to argument 2. Second, applicant has referred to the first section of the example, where the DNA molecule encodes the protein, rather than the more correct portion of the example, where the DNA claim encompasses a DNA molecule that does not encode the

protein. Claim 6 recites "a sequence of nucleotides provided in SEQ ID NO:9" and claim 29 recites "a sequence of nucleotides which is at least 85% identical to SEQ ID NO:9." These sequences encompass more that the proteins recited in Group I. Therefore, the first part of example 39 does not apply and there is no shared technical feature found in the sequences. The only shared feature that could be applied is the shared property of antifungal or antibacterial activity in a *G. mellonella* peptide, which is disclosed by Schuhmann.

Regarding argument 2, the PCT rules do not require that there be prior art over the claims. Instead, PCT Rule 13.2 requires that the technical feature shared between the inventions define a contribution over the prior art. Therefore, it is not the claims, but rather the shared feature of the claims that must be found in the prior art if unity is to be broken. As stated above, the only shared feature that could be applied is the shared property of antifungal or antibacterial activity in a *G. mellonella* peptide, which is disclosed by Schuhmann.

Regarding argument 3, applicant has chosen to have polynucleotides examined, rather than peptides. Therefore, the question is not whether the peptides themselves share a common property and structure, but whether the polynucleotides share a common property and structure. Clearly, the polynucleotides share a common property (i.e., antifungal and/or antibacterial activity). However, the polynucleotides do not share a common structural feature. Claim 6 recites "a sequence of nucleotides provided in SEQ ID NO:9." Any sequence of nucleotides within SEQ ID NO:9 meets this limitation; therefore, no common structure is shared by the polynucleotides encompassed by the claims. In fact, applicant's arguments bear this out. Applicant states that the peptide disclosed by Schuhmann has only 33.3% identity to SEQ ID NO:4 over a very small 12 amino acid stretch, arguing that there is a lack of structural similarity between the peptide disclosed by Schuhmann and the instant peptides. However, the polynucleotide encoding this polypeptide meets the limitations of the claims by sharing *a* sequence of nucleotides and by having antibacterial activity.

Regarding argument 4, there are peptides encoded by the polynucleotides of Group II which are defensins. Therefore, the peptides encompassed clearly do not belong to a separate class of peptides from defensins.

Newly submitted claims 28 and 29 are part of Groups I and II, respectively, as set forth in the restriction requirement of 4/25/2008. Claims 1, 5, 11-12, 14, 16-18, and 20-21, 23, 25, and 27-28 are withdrawn as being drawn to nonelected inventions. Claims 6, 8-10, 13, 15, and 29 are currently under examination.

Information Disclosure Statement

The information disclosure statement filed on 3/13/2009 has been considered. An initialed copy is enclosed.

Objections Withdrawn

The objection to the specification for the use of the trademark FICOLL, is withdrawn in light of applicant's amendment thereto.

The objection to claim 6 because it depends from a nonelected claim is withdrawn in light of applicant's amendment thereto.

New Objections

Claim 29 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In addition, claim 29 includes nonelected subject matter.

Claim Rejections Withdrawn

The rejection of claim 15 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in light of applicant's arguments. Applicant correctly points out the features of moricins that are common to those known in the art and SEQ ID NO:4. Several variants are disclosed and, in particular, Hemmi (2002) discloses a detailed analysis of the tertiary structure and necessary features of moricins that are required for activity.

The rejection of claims 6, 8-10, 13, and 15 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated polynucleotides comprising the sequence of

SEQ ID NO:9, vectors and isolated host cells comprising said polynucleotides, and transgenic plants having been transformed with said polynucleotides which produce a polypeptide comprising SEQ ID NO:4, does not reasonably provide enablement for the full scope of the claims as drawn, is withdrawn in light of applicant's arguments. Applicant correctly points out the features of moricins that are common to those known in the art and SEQ ID NO:4. Several variants are disclosed and, in particular, Hemmi (2002) discloses a detailed analysis of the tertiary structure and necessary features of moricins that are required for activity.

The rejection of claims 6, 8-10, 13, and 15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in light of applicant's amendment thereto.

Claim Rejections Maintained

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 6, 8-10, 13, and 15 under 35 U.S.C. 102(b) as being anticipated by Altier *et al.* (WO 02/086072 A2, 2002; IDS filed 8/24/2006), is maintained for the reasons set forth in the previous office action.

Applicant argues:

1. That the claims have been amended to clarify that the fragments must be biologically active (which means that the fragments must have antibacterial and/or antifungal activity). Applicant argues that the 3 amino acid region disclosed by Altier could not have the antibacterial and/or antifungal activity required by the claims. Applicant also argues that Altier does not disclose a peptide or polynucleotide having 80% identity to a sequence recited in teh present claims.

Applicant's arguments have been fully considered and deemed non-persuasive.

The rejection was not based on the fragment language found in the claims. Claim 6 recites "a sequence of nucleotides provided in SEQ ID NO:9." Any sequence of nucleotides within SEQ ID NO:9 meets this limitation. There is no need for the portion of SEQ ID NO:9 to have a biological activity, so long as the peptide encoded by the entire polynucleotide has antibacterial and/or antifungal activity. Likewise, claim 15 recites "an amino acid sequence as provided in SEQ ID NO:4." Again, *an* amino acid sequence includes any sequence found (or provided) in SEQ ID NO:4.

As outlined previously, the instant claims are drawn to an isolated polynucleotide that comprises a sequence of nucleotides provided in SEQ ID NO:9, a sequence of nucleotides which is at least 80% identical to SEQ ID NO:9, as well as a vector comprising said polynucleotide and a host cell comprising said polynucleotide. The claims are also drawn to a transgenic plant that has been transformed with a polynucleotide that comprises a sequence of nucleotides provided in SEQ ID NO:9, a sequence of nucleotides which is at least 80% identical to SEQ ID NO:9, or a sequence that hybridizes to either of these under high stringency conditions. Said transgenic plant must produce a peptide with an amino acid sequence as provided in SEQ ID NO:4, an amino acid sequence which is at least 80% identical to SEQ ID NO:4, a biologically active fragment of these, or a precursor comprising these sequences. Said peptide must exhibit antifungal and/or antibacterial activity.

Altier *et al.* disclose disease resistance-conferring DNA constructs for expression in plants (see page 38-39). These constructs comprise DNA with a sequence (SEQ ID NO:1 that has nucleotides 151-153 in common with nucleotides 37-39 of the instantly claimed SEQ ID NO:9) that encodes SEQ ID NO:2, which has amino acids 50-52 in common with amino acids 13-15 of the instantly claimed SEQ ID NO:4.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/
Examiner, Art Unit 1645

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645